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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,642

04/08/2004

Eric G. Lovett

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09/07/2006

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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/820,642

Applicant(s)

LOVETT ET AL.

Examiner

Kristen Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 8/8/05 (IDS).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 9-12, 45, 46, 58 and 59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 13-44, 47-57, 60-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/8/04, 8/8/05
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims directed to the following patentably distinct species:  
  
I - external cardiac device with transcutaneous electrodes of Fig. 6.  
  
II - implantable cardiac device with implantable electrodes of Fig. 7.
2. The species are independent or distinct because they do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, species I and II are mutually exclusive, not capable of use together, are not obvious variants and have a materially different mode of operation.
3. Because these species are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 37 and 50 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the *allowance* of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. During a telephone conversation with Mark Hollingsworth on 8/23/06 a provisional election was made with traverse to prosecute species II, claims 1-8, 13-44, 47-57 and 60-62. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-12, 45-46 and 58-59 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Specification***

6. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, *if* the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

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7. The specification contains references to a commonly owned patent application without application numbers. The examiner respectfully requests that this information be updated along with any other referenced applications without application numbers or referenced applications that have since issued.

8. The specification contains references co-pending applications by their application numbers. Some or all of these applications have since been issued. The examiner respectfully requests that the parent application information be updated in the specification along with any other referenced application numbers in the specification that have matured into patents.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-5, 8, 13-14, 19-25, 28-29, 33-41, 44, 47-54, 57 and 60-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Bardy et al. (2002/0035376).

Regarding claim 1, Bardy shows a system comprising detection circuitry, energy delivery circuitry; one or more electrodes configured for subcutaneous non-intrathoracic placement and for coupling to the detection circuitry and energy delivery circuitry, and a controller coupled to the detection circuitry and energy delivery circuitry, the controller, in response to a cardiac condition requiring treatment, coordinating delivery of a selected *one of* the tachycardia,

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bradycardia, and asystole prevention therapies (Paragraphs [0039], [0040], [0043]; Figs. 4-6, 9, 11, 15).

With respect to claim 21, Bardy shows a system including a housing configured for subcutaneous, non-intrathoracic placement; detection circuitry provided in the housing, energy delivery circuitry provided in the housing, one or more electrodes configured for subcutaneous, non-intrathoracic placement and coupled to the detection circuitry and energy delivery circuitry, and a controller provided in the housing and coupled to the detection circuitry and energy delivery circuitry, the controller, in response to a cardiac condition requiring treatment, delivering a selected *one of* the tachycardia, bradycardia, and asystole prevention therapies (Paragraphs [0039], [0040], [0043]; Figs. 4-6, 9, 11, 15).

Regarding claim 37, Bardy shows a method including sensing cardiac activity from a subcutaneous, non-intrathoracic location detecting a cardiac condition necessitating treatment in response to the sensed cardiac activity, and delivering *one of* a plurality of cardiac therapies to treat the detected cardiac condition, the plurality of cardiac therapies comprising at least a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy (Paragraphs [0039], [0040], [0043]; Figs. 4-6, 9, 11, 15).

The examiner has treated the “means for” limitations of claim 50 as invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. One with ordinary skill in the art will understand that the structure of the sensing circuitry (204) and subcutaneous electrodes (214) will perform the recited function of “sensing cardiac activity from a subcutaneous non-intrathoracic location”, and the diagnostics circuitry (210) will perform the recited function of “detecting a cardiac condition in response to

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the sensed cardiac activity” and the shock therapy circuitry (216) and pacing therapy circuitry (230) will perform the function of “delivering one of a plurality of cardiac therapies”.

The examiner considers that Bardy shows equivalent structure to the means for sensing cardiac activity from a subcutaneous, non-intrathoracic location, the means for detecting a cardiac condition necessitating treatment in response to the sensed cardiac activity, and the means for delivering *one of* a plurality of cardiac therapies to treat the detected cardiac condition, the plurality of cardiac therapies comprising at least a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy (Paragraphs [0039], [0040], [0043]; Figs. 4-6, 9, 11, 15).

Regarding claims 2-5, 22-25, 38-41 and 51-54, Bardy shows the plurality of cardiac therapies comprises a bradycardia pacing, cardiac resynchronization (cardioversion/defibrillation) antitachycardia pacing, and defibrillation (Paragraphs [0039], [0040]).

With respect to claims 8 and 28, Bardy shows the one or more electrodes are configured for cardiac pacing (15, 27, 27', 1417, 1219) and sensing (23, 25, 26, 28, 1425, 1427) (Figs. 1-3, 10, 12-14, 18).

Regarding claim 13, Bardy shows a housing where the circuitry is situated and the housing is configured for implantation (Figs. 1-3, 10, 12-14, 18).

With respect to claims 14 and 29, Bardy shows the one or more electrodes include at least one electrode (15, 26, 28, 1417, 1219, 1425, 1427) disposed on the housing (Figs. 1-3, 10, 12-14, 18).

Regarding claims 19 and 33, Bardy shows a housing within which the detection circuitry, energy delivery circuitry, and controller are situated, the housing is configured for implantation

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in a patient and the one or more electrodes (15, 26, 28, 1417, 1219, 1425, 1427) are disposed in or on the housing (Figs. 1-3, 10, 12-14, 18).

With respect to claims 20 and 34, Bardy shows the housing is configured to have an arcuate shape (Figs. 12-14, 18).

Regarding claims 35-36, Bardy shows the one or more electrodes (23, 25, 26, 27, 27', 28) comprise at least one subcutaneous, non-intrathoracic electrode array coupled to the housing via a lead (21) (Figs 1-6, 9-13)

With respect to claims 44, 48, 57 and 60, Bardy shows detecting the cardiac condition at a subcutaneous, non-intrathoracic location (via electrodes 23, 25, 26, 28, 1425, 1427) and energy for the plurality of cardiac therapies is provided from a subcutaneous, non-intrathoracic source (within the housing) (Figs. 1-3, 10, 12-14, 18).

Regarding claims 48-49 and 61-62, Bardy shows delivering monophasic waveforms and delivering multiphasic waveforms (Paragraphs [0039], [0063], [0071]).

The examiner has treated the “means for” limitations of claims 57 and 60-62 as invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. One with ordinary skill in the art will understand that the structure of the sensing circuitry (204) and subcutaneous electrodes (214) and diagnostics circuitry (210) will perform the recited function of “detecting the cardiac condition at a subcutaneous non-intrathoracic location”, the structure of the power source (220) will perform the recited function of “supplying energy . . . from a subcutaneous non-intrathoracic source” and the shock therapy circuitry (216) and pacing therapy circuitry (230) will perform the function of “delivering monophasic waveforms” and “delivering multiphasic waveforms”



As explained above, the examiner considers that Bardy shows equivalent structure to the means for detecting the cardiac condition at a subcutaneous non-intrathoracic location, the means for supplying energy . . . from a subcutaneous non-intrathoracic source, the means for delivering monophasic waveforms and the means for delivering multiphasic waveforms. See rejections above for claims 57 and 60-62.

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

11. Claims 1-5, 8, 13-25, 28-41, 44, 47-54, 57 and 60-62 are rejected under 35 U.S.C. 102(a) as being anticipated by Bardy et al. (2002/0091414).

Regarding claim 1, Bardy shows a system comprising detection circuitry, energy delivery circuitry; one or more electrodes configured for subcutaneous non-intrathoracic placement and for coupling to the detection circuitry and energy delivery circuitry, and a controller coupled to the detection circuitry and energy delivery circuitry, the controller, in response to a cardiac condition requiring treatment, coordinating delivery of a selected *one of* the tachycardia, bradycardia, and asystole prevention therapies (Paragraphs [0035], [0036], [0039]; Figs. 4-6, 9, 11, 15).

With respect to claim 21, Bardy shows a system including a housing configured for subcutaneous, non-intrathoracic placement; detection circuitry provided in the housing, energy delivery circuitry provided in the housing, one or more electrodes configured for subcutaneous, non-intrathoracic placement and coupled to the detection circuitry and energy delivery circuitry, and a controller provided in the housing and coupled to the detection circuitry and energy delivery circuitry, the controller, in response to a cardiac condition requiring treatment,

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delivering a selected *one of* the tachycardia, bradycardia, and asystole prevention therapies (Paragraphs [0035], [0036], [0039]; Figs. 4-6, 9, 11, 15).

Regarding claim 37, Bardy shows a method including sensing cardiac activity from a subcutaneous, non-intrathoracic location detecting a cardiac condition necessitating treatment in response to the sensed cardiac activity, and delivering *one of* a plurality of cardiac therapies to treat the detected cardiac condition, the plurality of cardiac therapies comprising at least a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy (Paragraphs [0035], [0036], [0039]; Figs. 4-6, 9, 11, 15).

The examiner has treated the “means for” limitations of claim 50 as invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. One with ordinary skill in the art will understand that the structure of the sensing circuitry (204) and subcutaneous electrodes (214) will perform the recited function of “sensing cardiac activity from a subcutaneous non-intrathoracic location”, and the diagnostics circuitry (210) will perform the recited function of “detecting a cardiac condition in response to the sensed cardiac activity” and the shock therapy circuitry (216) and pacing therapy circuitry (230) will perform the function of “delivering one of a plurality of cardiac therapies”.

The examiner considers that Bardy shows equivalent structure to the means for sensing cardiac activity from a subcutaneous, non-intrathoracic location, the means for detecting a cardiac condition necessitating treatment in response to the sensed cardiac activity, and the means for delivering *one of* a plurality of cardiac therapies to treat the detected cardiac condition, the plurality of cardiac therapies comprising at least a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy (Paragraphs [0035], [0036], [0039]; Figs. 4-6, 9, 11, 15).

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Regarding claims 2-5, 22-25, 38-41 and 51-54, Bardy shows the plurality of cardiac therapies comprises a bradycardia pacing, cardiac resynchronization (cardioversion/defibrillation) antitachycardia pacing, and defibrillation (Paragraphs [0035], [0036]).

With respect to claims 8 and 28, Bardy shows the one or more electrodes are configured for cardiac pacing (15, 27, 27', 1417, 1219) and sensing (23, 25, 26, 28, 1425, 1427) (Figs. 1-3, 10, 12-14, 18).

Regarding claim 13, Bardy shows a housing where the circuitry is situated and the housing is configured for implantation (Figs. 1-3, 10, 12-14, 18).

With respect to claims 14 and 29, Bardy shows the one or more electrodes include at least one electrode (15, 26, 28, 1417, 1219, 1425, 1427) disposed on the housing (Figs. 1-3, 10, 12-14, 18).

Regarding claims 15-18 and 30-32, Bardy shows delivering therapy of pacing pulses at a rate varying between 2 and 40 pulses per minute (20-120 stimuli per minute, where in the lower end of the range near 20 stimuli per minute, consciousness would not be restored) (Paragraph [0078])

Regarding claims 19 and 33, Bardy shows a housing within which the detection circuitry, energy delivery circuitry, and controller are situated, the housing is configured for implantation in a patient and the one or more electrodes (15, 26, 28, 1417, 1219, 1425, 1427) are disposed in or on the housing (Figs. 1-3, 10, 12-14, 18).

With respect to claims 20 and 34, Bardy shows the housing is configured to have an arcuate shape (Figs. 12-14, 18).

Regarding claims 35-36, Bardy shows the one or more electrodes (23, 25, 26, 27, 27', 28) comprise at least one subcutaneous, non-intrathoracic electrode array coupled to the housing via a lead (21) (Figs 1-6, 9-13)

With respect to claims 44, 48, 57 and 60, Bardy shows detecting the cardiac condition at a subcutaneous, non-intrathoracic location (via electrodes 23, 25, 26, 28, 1425, 1427) and energy for the plurality of cardiac therapies is provided from a subcutaneous, non-intrathoracic source (within the housing) (Figs. 1-3, 10, 12-14, 18).

Regarding claims 48-49 and 61-62, Bardy shows delivering monophasic waveforms and delivering multiphasic waveforms (Paragraphs [0035], [0060], [0072]).

The examiner has treated the "means for" limitations of claims 57 and 60-62 as invoking 35 U.S.C. 112, 6<sup>th</sup> paragraph. One with ordinary skill in the art will understand that the structure of the sensing circuitry (204) and subcutaneous electrodes (214) and diagnostics circuitry (210) will perform the recited function of "detecting the cardiac condition at a subcutaneous non-intrathoracic location", the structure of the power source (220) will perform the recited function of "supplying energy . . . from a subcutaneous non-intrathoracic source" and the shock therapy circuitry (216) and pacing therapy circuitry (230) will perform the function of "delivering monophasic waveforms" and "delivering multiphasic waveforms"

As explained above, the examiner considers that Bardy shows equivalent structure to the means for detecting the cardiac condition at a subcutaneous non-intrathoracic location, the means for supplying energy . . . from a subcutaneous non-intrathoracic source, the means for delivering monophasic waveforms and the means for delivering multiphasic waveforms. See rejections above for claims 57 and 60-62.

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 6, 26, 42 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy et al. (2002/0035376) as applied to claims 1, 21, 37 and 50 above and further in view of Brockway et al. (4,562,841).

Bardy is as explained before. Although Bardy fails to show the cardiac therapy comprises a rate smoothing therapy, attention is directed to Brockway who teaches rate smoothing pacing therapy. Brockway teaches that a rate smoothing therapy operates to ensure that the pacing rate from pacing interval to pacing interval does not change by more than a selected percentage of the previous interval thus providing a smoother less erratic pacing rhythm. (Col. 6, lines 49-54). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the system and method of Bardy to include a rate smoothing pacing therapy in order to ensure that the pacing rate from pacing interval to pacing interval does not change by more than a selected percentage of the previous interval thus providing a smoother less erratic pacing rhythm.

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14. Claims 6, 26, 42 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy et al. (2002/0091414) as applied to claims 1, 21, 37 and 50 above and further in view of Brockway et al. (4,562,841).

Bardy is as explained before. Although Bardy fails to show the cardiac therapy comprises a rate smoothing therapy, attention is directed to Brockway who teaches rate smoothing pacing therapy. Brockway teaches that a rate smoothing therapy operates to ensure that the pacing rate from pacing interval to pacing interval does not change by more than a selected percentage of the previous interval thus providing a smoother less erratic pacing rhythm. (Col. 6, lines 49-54). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the system and method of Bardy to include a rate smoothing pacing therapy in order to ensure that the pacing rate from pacing interval to pacing interval does not change by more than a selected percentage of the previous interval thus providing a smoother less erratic pacing rhythm.

15. Claims 7, 27, 43 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy et al. (2002/0035376) as applied to claims 1, 21, 37 and 50 above and further in view of Kieval et al. (5,814,079).

Bardy is as explained before. Although Bardy fails to show the cardiac therapy comprises a sub-threshold stimulation therapy, attention is directed to Kieval who teaches a sub-threshold stimulation therapy. Kieval teaches that a sub-threshold stimulation therapy is used to prevent a tachyarrhythmia by effecting maximal cardiac relaxation and suppressing aberrant electrical activity (Abs) and sub-threshold stimulation therapy is used in combination with cardioversion/defibrillation therapy to reduce the cardioversion shock energy required (Col. 5,

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lines 31-47). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the system and method of Bardy to include a sub-threshold stimulation therapy in order to prevent a tachyarrhythmia by effecting maximal cardiac relaxation and suppressing aberrant electrical activity and also to reduce the cardioversion shock energy required.

16. Claims 7, 27, 43 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy et al. (2002/0091414) as applied to claims 1, 21, 37 and 50 above and further in view of Kieval et al. (5,814,079).

Bardy is as explained before. Although Bardy fails to show the cardiac therapy comprises a sub-threshold stimulation therapy, attention is directed to Kieval who teaches a sub-threshold stimulation therapy. Kieval teaches that a sub-threshold stimulation therapy is used to prevent a tachyarrhythmia by effecting maximal cardiac relaxation and suppressing aberrant electrical activity (Abs) and sub-threshold stimulation therapy is used in combination with cardioversion/defibrillation therapy to reduce the cardioversion shock energy required (Col. 5, lines 31-47). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the system and method of Bardy to include a sub-threshold stimulation therapy in order to prevent a tachyarrhythmia by effecting maximal cardiac relaxation and suppressing aberrant electrical activity and also to reduce the cardioversion shock energy required.

17. Claims 17-18 and 31-32 are rejected under 35 U.S.C. 103(a) as being obvious over Bardy et al. (2002/0035376) as applied to claims 1, and 21 above and further in view of Lovett et al. (2004/0215258).

Bardy is as explained before. Although Bardy fails to show the asystole prevention therapy comprises delivery of pacing pulses at a rate lower than a pacing rate associated with the bradycardia therapy, cardiac therapy comprises a sub-threshold stimulation therapy, attention is directed to Kieval who teaches a sub-threshold stimulation therapy. Kieval teaches that a sub-threshold stimulation therapy is used to prevent a tachyarrhythmia by effecting maximal cardiac relaxation and suppressing aberrant electrical activity (Abs) and sub-threshold stimulation therapy is used in combination with cardioversion/defibrillation therapy to reduce the cardioversion shock energy required (Col. 5, lines 31-47). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the system and method of Bardy to include a sub-threshold stimulation therapy in order to prevent a tachyarrhythmia by effecting maximal cardiac relaxation and suppressing aberrant electrical activity and also to reduce the cardioversion shock energy required.

### *Conclusion*

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

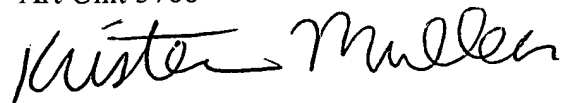


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kristen Mullen  
Patent Examiner  
Art Unit 3766

kdm

A handwritten signature in black ink that reads "Kristen Mullen". The signature is written in a cursive style with a large, stylized "K" and "M".